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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,685	11/28/2000	Steven G. Reed	014058-008561US	7839

20350 7590 01/25/2008

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EXAMINER
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SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

MAIL DATE	DELIVERY MODE
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01/25/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

09/724,685

**Applicant(s)**

REED ET AL.

**Examiner**

Rodney P. Swartz, Ph.D.

**Art Unit**

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 37-41 and 56-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 37-41, 56-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
    Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
    Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Applicants' Response to Office Action, received 5 November 2007, is acknowledged.

Claims 37 and 56 have been amended.

2. Claims 37-41 and 56-59 are pending and under consideration.

### Rejections Withdrawn

3. The rejection of claims 37-41 and 56-59 under 35 USC 112, second paragraph, indefiniteness, is withdrawn in light of the amendment of the claims.

### Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 38-41 and 56-49 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4, 6, 9, 24, 27, and 28 of U.S. Patent No. 7,083,796.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a fusion protein comprising a polypeptide

comprising SEQ ID NO:107, and compositions comprising the fusion protein and a carrier and an adjuvant. Instant SEQ ID NO:107 is identical to SEQ ID NO:14 in U.S. Pat. No. 7,083,796. The claims 4, 6, 9, 24, 27, and 28 of U.S. Patent No. 7,083,796 drawn to a fusion protein comprising SEQ ID NO:14 (and therefore, a protein comprising  $\geq 9$  amino acids of instant SEQ ID NO:107), and compositions comprising the fusion protein and a carrier and an adjuvant.

6. Claims 37-41 and 56-49 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 7,122,196.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a polypeptide comprising SEQ ID NO:107, or a fusion protein comprising a polypeptide comprising SEQ ID NO:107, and compositions comprising the fusion protein and a carrier and an adjuvant. Instant SEQ ID NO:107 is identical to SEQ ID NO:102 in U.S. Pat. No. 7,122,196. The claims 1-5 of U.S. Patent No. 7,122,196 are drawn to an isolated polypeptide comprising SEQ ID NO:102 or an immunogenic portion of SEQ ID NO:102, and a fusion protein comprising SEQ ID NO:102 and compositions comprising the fusion protein and a carrier and an adjuvant.

7. Claims 37-41 and 56-49 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 and 8-13 of U.S. Patent No. 7,261,897.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a polypeptide comprising SEQ ID NO:107, or a fusion protein comprising a polypeptide comprising SEQ ID NO:107, and compositions comprising the fusion protein and a carrier and an adjuvant. Instant SEQ ID NO:107 is identical to SEQ ID NO:8 in U.S. Pat. No. 7,261,897. The claims 1-5 and 8-13 of U.S. Patent No. 7,261,897 are drawn to an isolated polypeptide comprising SEQ ID NO:8 or an

immunogenic portion of SEQ ID NO:8 (95% identical to SEQ ID NO:8), and a fusion protein comprising SEQ ID NO:8 and compositions comprising the fusion protein and a carrier and an adjuvant.

Claims 38-41 and 57-59 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 89-94 and 96-103 of copending Application No. 11/418,848. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a polypeptide comprising SEQ ID NO:107, or a fusion protein comprising a polypeptide comprising SEQ ID NO:107, and compositions comprising the fusion protein and a carrier and an adjuvant. Instant SEQ ID NO:107 is identical to SEQ ID NO:14 in copending Application No. 11/418,848. The claims 89-94 and 96-103 of copending Application No. 11/418,848 are drawn to a fusion polypeptide comprising SEQ ID NO:14 or an immunogenic portion of SEQ ID NO:14 (95% identical to SEQ ID NO:14), and a fusion protein comprising SEQ ID NO:14 and compositions comprising the fusion protein and a carrier and an adjuvant.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### **Conclusion**

8. No claims are allowed.
9. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 7:30 PM EST.


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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Shannon Foley, can be reached on (571)272-0898.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
RODNEY P. SWARTZ, PH.D.  
PRIMARY EXAMINER  
Art Unit 1645

January 14, 2008